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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FREDMAN, JEFFREY NORMAN	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,755	WENZ, HANS-MICHAEL	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *131-144* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *131-144* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12/1/04 4/11/03
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2004 has been entered.

Status

2. Claims 131-144 are pending.

Claims 131-144 are rejected.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Claim Interpretation

3. In the claims, the new limitation "amplified from a plurality of different loci" can be construed in at least two different ways. The broadest interpretation is that different loci represent any two sequences which are different. Under this interpretation, even a single base change would result in the sequence being a different loci. A narrower interpretation is based upon a requirement that the loci are physically separated. Since the specification at the cited page 43 does not define the term loci, rejections will be made against both the broad and narrow interpretation of this phrase. The 102 rejection

will be maintained against the broad reading of the claim and a new 103 rejection will be made to address the narrower interpretation.

4. In the claims, the term "addressable support specific portion" is interpreted as a nucleic acid that can bind a complementary nucleic acid probe. Any nucleic acid sequence whatsoever can meet this limitation since any nucleic acid sequence can hybridize to the complementary sequence by Watson-Crick base pairing.

5. In the claims, the term "mobility modifier" is read (in context of the claim that requires at least two such modifiers) as requiring two nucleic acids that can bind to two different "amplification products" (as broadly defined above) which differ either in their length, or in the label that is attached to them. Applicant is correct that the limitation can be even broader than interpreted above. However, the above explanation is intended to indicate how the prior art cited below is applied.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 131-134 and 136-144 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedhoff et al (Anal. Biochem. (1993) 215:9-16).

Friedhoff teaches a composition of claims 131 and 141 comprising

(i) a plurality of different amplification products (see page 11, figure 1 and page 12, column 1, subheading "Polymerase Chain Reaction", where there are two

different amplification products, with either a AT or GC basepair at the SNP site) which comprise;

(a) a first primer specific portion (see page 12, column 2, where both different amplification products are amplified using a common upstream primer),

(b) a second primer specific portion (see page 12, column 2, where both different amplification products are amplified using a common downstream primer)

(c) and an addressable support specific portion, between the primer specific portions that is different for each of the amplification products (see page 11, figure 1, where one amplification product has an AT basepair and the other a GC basepairs that is distinct)

and

(ii) at least two different mobility modifiers, (see figure 1 and page 12, where the two probes, the Fluorescein labeled and digoxigen labeled probes that bind to the addressable support specific portion represent two different sequence specific mobility modifiers) which further comprises:

(a) a tag complement for specifically binding the addressable support specific portion of one of the plurality of different amplification products (See figure 1 and page 12, where the two probes each bind to the proper amplified PCR products),

(b) a tail which imparts to each mobility modifier a distinct mobility relative to the other mobility modifiers (see figure 1 and page 12, where each of the probes has a different chemical label with a different molecular mass that would result in a different mobility, one of which is fluorescein, the other of which is digoxigenin)

With regard to claims 132, 137, 142, all of the addressable support specific portions are substantially the same length (see figure 1, and page 10 where each probe is 24 nucleotides in length),

With regard to claims 133, 138,143, each of the mobility modifiers has a label, one of which is digoxigenin, the other of which is fluorescein (see page 10, column 2 and figure 1).

With regard to claims 134, 139, 144, the second primer specific portion is the same for each different amplification product (see figure 1 and page 12).

With regard to claims 136 and 140, these claims requires that the sequence specific mobility modifiers do not cross hybridize to the same addressable support specific portion. Since hybridization specificity depends upon conditions and since conditions can be designed which distinguish oligonucleotides which differ from a single nucleotide, the oligonucleotides of Friedhoff can be analyzed under conditions where they will not cross hybridize.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 131-144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins (APMIS (1991) 99:667-673) in view of Grossman et al (U.S. Patent 5,514,543).

Jenkins teaches a composition comprising

(i) a plurality of different amplification products drawn to different loci (see figure 2, page 669, where multiple different HPV types were amplified and the probes used hybridize to different physical areas of the HPV genome as shown in figure 1) which comprise;

(a) a first primer specific portion (see page 668, column 1, where common primers are used),

(b) a second primer specific portion (see page 668, column 1, where a second primer specific region is present)

(c) and an addressable support specific portion, between the primer specific portions that is different for each of the amplification products (see figure 1, where each amplification product includes a distinct HPV region) and

(ii) at least two different probes for detection of the different amplification products, (see figure 1) which further comprises:

(a) a tag complement for specifically binding the addressable support specific portion of one of the plurality of different amplification products (See figure 1, where at least three different probes to different HPV types are present),

With regard to claim 135, Jenkins teaches three different probes (see figure 1).

With regard to claims 132, 137, 142, all of the addressable support specific portions are substantially the same length (see figure 1),

With regard to claims 134, 139, 144, the second primer specific portion is the same for each different amplification product (see figure 1).

With regard to claims 136 and 140, these claims requires that the sequence specific mobility modifiers do not cross hybridize to the same addressable support specific portion. The probes of Jenkins will not cross hybridize since they are drawn to different sequences (see figure 1).

Jenkins does not teach a tail which imparts to each mobility modifier a distinct mobility relative to the other mobility modifiers.

Grossman expressly teaches a method for detection of amplified nucleic acids with unique sequences (see figure 19) with the steps of:

combining the one or more amplification products with at least two different sequence-specific mobility-modifiers, wherein each different mobility-modifier is capable of sequence-specific binding to a different addressable support-specific portion (see column 22, lines 10-17) and comprises (a) a tag complement for specifically binding the addressable support- specific portion of one of the one or more amplification products (see column 22, lines 10-17), and (b) a tail which imparts to each mobility modifier a mobility that is distinctive relative to the mobilities of one or more other of said at least two different mobility-modifiers in a mobility-dependent analysis technique (see column 22, lines 28-32),

removing mobility-modifiers that are not sequence-specifically bound to the one or more amplification products from mobility-modifiers that are sequence-specifically bound to the one or more amplification products (see column 22, lines 24-26),

releasing the sequence-specifically bound mobility-modifiers from the one or more amplification products (see column 22, lines 26-27),

subjecting the released mobility-modifiers to a mobility-dependent analysis technique (see column 22, lines 30-32); and

detecting the one or more target sequences in the sample by detecting distinctive positions of the mobility-modifiers (see column 22, lines 30-32).

With regard to claims 133, 138,143, Grossman teaches that each of the probes has a label (see abstract, for example).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the mobility modifiers of Grossman with the probe detection method of Jenkins in order to obtain advantages suggested by Grossman that the method permits "a rapid, single assay format for detecting the presence or absence of multiple selected sequences in a polynucleotide sample (see column 2, lines 61-63)." An ordinary practitioner would have been motivated to use the mobility modifiers of Grossman in oder to permit more accurate and simple single assay detection of the different HPV types of Jenkins.

Response to Arguments

11. Applicant's arguments filed October 1, 2004 have been fully considered but they are not persuasive.

Applicant argues that Friedhoff does not teach "different loci". As noted in the claim interpretation section above, this phrase, not defined in any way by the specification, may be read either broadly or narrowly. As noted above, Friedhoff remains applicable under a broad reading of the term "different loci".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
1/21/05